

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF NEW YORK

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UNITED STATES OF AMERICA,

Plaintiff,

Case No. 14-cr-0208 (ADS)

-against-

WILLIAM SCULLY

Defendant.

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**NON-PARTY JERSEY HEMEONC LLC'S MEMORANDUM OF LAW
IN SUPPORT OF ITS MOTION TO QUASH DEFENDANT'S SUBPOENA**

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PRELIMINARY STATEMENT

Jersey HemeOnc, LLC (“HemeOnc” or “Movant”) is not a party to this action. By cover letter dated July 20, 2015, William Scully (“Defendant”) served a subpoena on Movant. Defendant’s subpoena is returnable August 24, 2015, and it seeks a broad spectrum of Movant’s confidential and proprietary business documents for a period of more than five years: from January 1, 2010 to the present.

HemeOnc requests that Defendant’s subpoena be quashed for several reasons. First, substantially all of the documents sought through Defendant’s subpoena are subject to the privacy requirements of the Health Insurance Portability and Accountability Act (“HIPAA”) and the underlying regulations which bar their disclosure in most circumstances, including in response to a subpoena, unless certain mandated measures are in place. Those protective measures are not in place in this case.

Second, substantially all the documents and information sought by the subpoena are Movant’s confidential and proprietary documents and Movant is not party in this action.

Third, assuming the Defendant is able to successfully move beyond the above barriers, the scope of Defendant’s subpoena is so broad that it will necessarily involve a substantial amount of time and human resources of the Movant in addition to imposing substantial costs on the Movant. HemeOnc is a small medical practice, without appropriate human and technology resources that would allow it to gather, compile and respond to Defendant’s far-reaching, inexact subpoena that essentially seeks substantially all of Movant’s business records and information for the past five years. The subpoena imposes additional requirements, indeed burdens, on the Movant beyond gathering and producing documents. For instance, the subpoena seeks to compel the Movant to gather and provide even those documents in the possession of Movant’s “agents

such as financial institutions, attorneys, and/or accountants”. By way of further example, the instructions to the subpoena request the Movant to provide detailed information concerning “Lost Documents” *for each category of documents sought by the subpoena*; this requirement is more akin to an interrogatory request and not one found in a document subpoena.

Furthermore, inasmuch as substantially all the documents and information sought by the subpoena seeks documents that contain protected health information subject to HIPAA’s privacy requirements, the Movant will have to incur substantial legal fees to have its counsel review and analyze all of the responses to the subpoena in order to ensure compliance with HIPAA and its underlying regulations.

DISCUSSION

For the Court's convenience, Defendant's subpoena seeks the following, while using broadly defined terms:

1. All order forms, invoices, shipping records, and payments made for Altuzan, Aclasta, or Mabthera.
2. All Communications (including emails) regarding the drugs Altuzan, Aclasta, or Mabthera.
3. All submissions to any insurance company, Medicare, or Medicaid for reimbursement for the drugs Altuzan, Aclasta, or Mabthera (with all patient identifying information redacted).
4. All submissions to any patient insurance company, Medicare, or Medicaid for reimbursement for any of the drugs listed in the invoice attached as Exhibit A (with all patient identifying information redacted).
5. All Communications (including emails) with Special Agent Thomas Nasiatka or any other representative of the FDA regarding any of the Relevant Individuals, or regarding Medical Device King or Pharmacological.
6. All Documents and Communications regarding any criminal charges of which you have been accused or to which you have pled guilty in any court in the United States.
7. All Documents and Communications regarding any civil or administrative charges by the FDA of which you have been accused or to which you have admitted.

A copy of Defendant's subpoena and the cover letter of Defendant's counsel is attached as Exhibit A to the Affirmation of Vafa Sarmasti, Esq. ("Sarmasti Affirm.")

I. Defendant's Subpoena seeks documents and information containing individually identifiable health information of patients that are subject to HIPAA privacy requirements.

Items 2 through 5 of Defendant's subpoena seek documents and information that contains "individually identifiable health information" of patients that is subject to HIPAA privacy requirements. Inasmuch as item 2 broadly seeks all communications regarding the drugs Altuzan,

Alcasta, and Mabthera as opposed to limiting the request to communications with Defendant, compliance with the request will necessarily require Movant to include all persons including patients, pharmacies and other physicians or healthcare providers that treat(ed) patients.

“Individually identifiable health information” means “any information, including demographic information collected from an individual, that (A) is created or received by a health care provider, health plan, employer ... and (B) relates to past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual, and (i) identifies the individual; or (ii) with respect to which there is a reasonable basis to believe that the information can be used to identify the individual.” 45 U.S.C. §1320d (6); *see also* 45 C.F.R. §160.103.

Absent the patients’ consent to disclosure, a health care provider may not disclose patients’ individually identifiable health information in response to a subpoena or discovery unless the health care provider has received (1) satisfactory assurance from the party requesting the documents that s/he has made reasonable efforts to ensure that the individual who is the subject of the protected health information has been given notice of the request; or (2) that reasonable efforts have been made by the requesting party to secure a qualified protective order from this court that (A) prohibits the parties from using or disclosing the protected health information for any purpose other than the litigation proceeding for which such information was requested; and (B) requires the return of the health care provider or destruction of the protected health information (including all copies made) at the of the litigation or proceeding. *See* 45 C.F.R. §164.512(e). *See e.g.*, Babcock v. C-Tech Collections, Inc., 2014 U.S. Dist. LEXIS

112425 (E.D.N.Y.); U.S. v. Metropolitan Ambulance & First-Aid Corp., 395 F. Supp. 2d 1 (E.D.N.Y. 2005).

The Defendant has not undertaken any steps to notify the Movant's patients given the identity of those patients are unknown to the Defendant. Further, Movant's counsel has reviewed the docket entries in this case and it appears Defendant never sought and therefore this Court has not entered a HIPAA compliant qualified protective order as required by 45 C.F.R. §164.512(e).

Items 3 through 5 of the subpoena direct the movant to redact all "patient identifying information". That however does not resolve the issue. First, it is not clear from the subpoena what the Defendant means by "patient identifying information". Defendant's undefined term however seems to refer to something less than "individually identifiable health information" inasmuch as "individually identifiable health information" is defined to include indirect information with respect to which there is a reasonable basis to believe that the information can be used to identify the individual. 45 U.S.C.A. §1320d (6); *see also* 45 C.F.R. §160.103.

Further, Movant respectfully notes that any order requiring Movant to redact all individually identifiable health information from such documents will impose a significant cost on the Movant inasmuch as Movant will have to have counsel painstakingly review all documents for Movant prior to production in order to ensure compliance with HIPAA regulations.

II. Items 2 through 5 of the Subpoena request documents that contain HemeOne's confidential and proprietary patient information.

Items 2 through 5 of Defendant's subpoena seek documents that contain Movant's confidential and proprietary patient information and patient list. Patient lists and patient identities often are treated as confidential information. *See Alan Dampf, P.C. v. Bloom*, 127

A.D.2d 719 (2nd Dept., 1987). As indicated above, the identity of those patients is also protected by HIPAA and its underlying regulations.

Here, Movant is not a party to this action, but the alleged victim of the Defendant's wrongful conduct. The subpoena however ignores that reality and seeks to have Movant provide all its confidential information and documents for the past five-plus years. Defendant's request moves well beyond that which Defendant needs and is likely aimed to harass the Movant in order to dissuade it from responding to any inquiries from the Government.

III. The Defendant's subpoena is broad, burdensome and harassing and seeks well beyond that which Defendant needs or is reasonably connected to this case.

Defendant's opposition Memorandum (DE 63) to the Government's motion (DE 61 and 62) reveals the scope of information that Defendant needs from non-parties to this case, which is far beyond that sought by Defendant's subpoena. A substantial portion of Defendant's opposition (10 out of 15 pages) is focused on documents and information Defendant needs from the Government, and more specifically, the U.S. Food and Drug Administration (FDA), but not necessarily non-parties such as the Movant.

In explaining Defendant's need for the documents and information sought by the subpoena, Defendant's opposition refers to one of the subpoena recipients, Dr. Jan Seski. According to Defendant, Defendant's counsel has learned that "the professional corporation of Dr. Seski pled guilty on September 19, 2013, to introducing unapproved new drugs into interstate commerce in violation of 21 U.S.C. §§331(d) and 355(a)" for having previously purchased drugs from persons similar to the Defendant. The Defendant therefore argues that such information belies the Government's argument and proves that the non-party purchasers from the Defendant(s) were not tricked or defrauded by the Defendant(s).

While that may seem to be a logical explanation, it fails to justify any of the categories in Defendant's subpoena, including items 6 or 7 of the subpoena to which the Defendant refers in his opposition memorandum as the reason for his subpoena. To explain, item 6 of Defendant's subpoena seeks "[a]ll Documents and Communications regarding any criminal charges of which you have been accused or to which you have pled guilty in any court in the United States" [emphasis added] from January 1, 2010 to the present. Instead of asking whether or not the Movant or its principal have been charged with or pled guilty to purchases of medication or similar drugs, the Defendant asks for all criminal charges and criminal pleas regardless of their nature or connection to the issues in Defendant's case. Arguably, pleading guilty to a speeding violation in Virginia (or similar states) which treat such offenses as misdemeanors falls within the scope of item 6 of Defendant's subpoena, though such information has absolutely no connection to the issues concerning Defendant. In fact, further broadening the scope of Defendant's subpoena is Defendant's use of defined terms such as "Documents" and "Communications". For instance, Defendant's subpoena broadly defines "Communications" to also include "conversations", "voicemail", "verbal interchange", "and other records of any Communications".

As to all the other items in the subpoena, Defendant's memorandum (DE 63) fails to provide any explanation that justifies Defendant's demand to non-party Movant to provide for the five-plus year period from January 1, 2010 to the present:

2. All Communications (including emails) regarding the drugs Altuzan, Aclasta, or Mabthera.
3. All submissions to any insurance company, Medicare, or Medicaid for reimbursement for the drugs Altuzan, Aclasta, or Mabthera (with all patient identifying information redacted).

4. All submissions to any patient insurance company, Medicare, Medicaid for reimbursement for any of the drugs listed in the invoice attached [to Defendant's subpoena] (with all patient identifying information redacted).
5. All Communications (including emails) with Special Agent Thomas Nasiatka or any other representative of the FDA regarding any of the Relevant Individuals, or regarding Medical Device King or Pharmalogical.

Defendant's subpoena is broad on its face, and Defendant has all but acknowledged that fact by failing to provide any explanation or hint in his memorandum (DE 63) as to why Defendant is seeking the items listed in 1 through 5 for a period expanding beyond five years.

A party seeking compliance with a subpoena must make a preponderance showing that the materials requested are relevant, *specifically identified*, and admissible. U.S. v. Barnes, 560 Fed. Appx. 36, 39-40; 2014 U.S. App. LEXIS 5293, at **3 (U.S.C.A., 2nd Cir.).

In U.S. v. RW Prof'l. Leasing Servs. Corp., 228 F.R.D. 158, 161-162; 2005 U.S. Dist. LEXIS 6725, this Court held that "[t]he purpose of Rule 17(c) is not to facilitate discovery, but to enable a party to obtain and inspect evidentiary material prior to trial". Citing to U.S. v. Cherry, 876 F. Supp. 547, 552 (S.D.N.Y. 1995), this Court further noted that Rule 17(c) should not be broadly interpreted as a discovery tool in criminal cases and that "courts must be careful that Rule 17(c) is not turned into a broad discovery device". *Quoting* U.S. v. Cuthertson, 630 F.2d 139, 146 (3rd Cir. 1980).

Here, Defendant's subpoena fails to specifically identify the documents it seeks, but instead embarks on a fishing expedition through a non-party's confidential documents and patients' HIPAA protected records. U.S. v. RW Prof'l. Leasing Servs. Corp., at 162 ("When determining whether a request for documents is specifically identified, the proponent must show that the subpoena is being used to obtain relevant evidence and not merely as a 'fishing expedition' to expand discovery.") Here, Defendants' subpoena (and their recent opposition memorandum at DE 63) fails to meet the specificity requirement because it does not reasonably

specify the information contained or believed to be contained in the documents sought; Defendant merely hopes that something useful may turn up. Id.

Here, based on the parties' filings with the Court, it seems Defendant's threshold issue is (or should have been) whether or not the Movant has been in a similar situation as Dr. Seski to which the Defendant refers in his papers – namely, whether or not the Movant or its principal have been previously charged with or pleaded guilty to a crime involved the unlawful sales of medications or drugs. If the Movant has not, then Defendant's subpoena is a fishing expedition.

CONCLUSION

For the foregoing reasons, Jersey HemeOnc, LLC respectfully requests the Court quash Defendant's subpoena.

Dated: August 21, 2015

Respectfully submitted,

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CERTIFICATE OF SERVICE

This certifies that on this 22nd day of August, 2015, the foregoing was electronically filed with the Clerk of the Court by using the CM/ECF system, which will send notification of such filing to all counsel of record. Courtesy hardcopies shall also be forwarded via Federal Express overnight delivery to The Honorable Arthur D. Spatt, U.S.D.J. United States District Court, 1024 Federal Plaza, Central Islip, New York 11722.

/s/ Vafa Sarmasti

Attorney for non-party Jersey HemeOnc LLC